days of its filing to determine whether the requirements of section 802(b)(3)(B) have been satisfied. Section 802(b)(3)(A) of the act requires that the agency publish a notice in the **Federal Register** within 10 days of the filing of an application for export to facilitate public participation in its review of the application. To meet this requirement, the agency is providing notice that Marian Merrell Dow Inc., Marian Park Dr., P.O. Box 9627, Kansas City, MO 64134–0627, has filed an application requesting conditional approval for the export of Anzemet (dolasetron Mesilate) Bulk Drug Substance to Italy for the preparation and packaging of the following injectable dose strengths 12.5 mg, 25 mg, 50 mg, 100 mg, and 200 mg for transshipment to the United Kingdom. Anzemet (dolasetron Mesilate) injection is indicated for nausea and vomiting in patients receiving initial and repeat courses of cancer chemotherapy (including high dose cisplatin) or radiotherapy and for post operative nausea and vomiting. The application was received and filed in the Center for Drug Evaluation and Research on August 8, 1995, which shall be considered the filing date for purposes of the act.

Interested persons may submit relevant information on the application to the Dockets Management Branch (address above) in two copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. These submissions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

The agency encourages any person who submits relevant information on the application to do so by September 11, 1995, and to provide an additional copy of the submission directly to the contact person identified above, to facilitate consideration of the information during the 30-day review period.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (sec. 802 (21 U.S.C. 382)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Center for Drug Evaluation and Research (21 CFR 5.44).

Dated: August 11, 1995.

Betty L. Jones,

Deputy Director, Office of Compliance, Center for Drug Evaluation and Research.

[FR Doc. 95–21453 Filed 8–29–95; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 95S–0193]

Pharmacology/Toxicology Electronic Submissions Pilot Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the Pharmacology/Toxicology (P/T) Electronic Submissions Pilot Project developed by the Center for Drug Evaluation and Research (CDER). This project is intended to increase the efficiency of both the investigational new drug application (IND) and the new drug application (NDA) review processes by providing for the electronic submission of preclinical P/T study reports. CDER is requesting that interested sponsors submit, on a voluntary basis, electronic copies of P/T study reports containing complete text and graphic material for review in word processor format, in addition to paper submissions.

FOR FURTHER INFORMATION CONTACT:

Regarding general information about the pilot project: Joseph F. Contrera, Center for Drug Evaluation and Research (HFD–400), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–4750.

Regarding technical information about participation in the pilot program: Patricia A. Sylvia, Center for Drug Evaluation and Research (HFD–72), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–3695.

SUPPLEMENTARY INFORMATION: CDER is exploring ways in which electronic submissions can be used to increase the efficiency of the drug review process. A key part of this process is the review of preclinical animal studies, most of which are conducted during the IND phase of the application. CDER has established a pilot project requesting that sponsors voluntarily submit electronic copies of P/T study reports, in addition to paper submissions. These reports would contain complete text and graphic material for review in word processor format. Electronic submissions of P/T study reports would allow for efficient storage and the capacity to retrieve, copy, and print pertinent sections of submissions for review.

This pilot project is expected to be most useful during the IND review process because the large proportion of preclinical P/T studies is submitted during this period. The agency believes that increasing the efficiency of the IND review process will have a positive effect on the NDA review process. If this pilot project is successful, CDER may consider acceptance of only electronic submissions. In the **Federal Register** of August 31, 1994 (59 FR 45160), FDA published a proposed rule entitled ''Electronic Signatures; Electronic Records.'' This pilot project is consistent with the goals of the proposed rule.

A description of the pilot project, as well as the general format and media specifications for electronic submissions, follows:

The Center for Drug Evaluation and Research (CDER) Pharmacology/Toxicology (P/T) Electronic Submissions

I. Background

CDER is exploring ways in which electronic submissions can be used to increase the efficiency of the drug review process. A key part of this process is the review of preclinical animal studies, most of which are conducted during the IND phase of the application. The Information Technology (IT) Subcommittee of the CDER Pharmacology/Toxicology Coordinating Committee (the P/T IT Subcommittee) is responsible for furthering the concept of electronic submissions for P/T reviews. In November 1994, after discussions between FDA and the Pharmaceutical Research and Manufacturers of America, three firms agreed to submit electronic preclinical P/T reports to CDER. In addition, CDER optically scanned P/T reports that were submitted in paper form, prepared reviews of these submissions electronically, and evaluated the utility of receiving the P/T submissions electronically. As a result of this experience, space has been allocated on the CDER Local Area Network (LAN) for P/T submissions and reviews, and the P/T IT Subcommittee agreed to solicit additional preclinical P/T electronic submissions from sponsors.

Each CDER reviewer is responsible for many IND's and NDA's that are in various stages of development and assigned different priorities. As a result, study reports may be stored in reviewers' offices for considerable periods of time until they can be reviewed. In addition, reviews often contain the results of multiple studies from amendments to an IND submitted at different times. This requires the storage, retrieval, collation, and merging of information from several studies into a single review. Electronic submissions of P/T reports would allow for efficient storage and the capacity to retrieve, copy, and print pertinent sections of submissions for review.

II. Objectives of Electronic Submission Pilot Project

A. Facilitate the Rapid and Convenient Retrieval of Information Contained in Submissions and Minimize Storage Space

A major time-consuming task for reviewers is searching through the large volume of paper submissions to find relevant documents when they are needed. Electronic documents and appropriate document

retrieval software make possible indexing of documents by content and the rapid retrieval of documents containing the desired information. The reviewer can electronically survey the document and copy or print those sections of the document that contain the required information. Electronic submissions will reduce the short-term and long-term storage space requirements and facilitate long-term retrieval of information.

B. Facilitate the Writing of Reviews

Currently, tabular or graphic material derived from a sponsor's paper submissions are either optically scanned and merged into a review or photocopied and physically pasted into a printed paper copy of a review. In the latter case, the table will not appear in electronic archival copies of the reviews. Electronic submissions will facilitate the ability of reviewers to copy portions of text, ''cut and paste'' tables or graphs, and incorporate them into a review. They will also allow the transfer of digital photographic images of histopathology or other images into a review in the near future.

C. Obtain Experience with Reviewing Electronic P/T Submissions and Make Recommendations for Expansion of the Pilot Program to Routine Use, Including Possible Elimination of Paper Submissions

The P/T IT Subcommittee intends to gain experience with the review of electronic P/T submissions, evaluate that experience, and develop recommendations on how electronic submissions can be used most efficiently in the P/T program. If electronic submissions can be successfully incorporated, CDER may consider acceptance of only electronic submissions. (See 59 FR 45160, August 31, 1994.) During the initial phase of the pilot program, CDER has a goal of receiving at least 10 toxicology study reports electronically. CDER now has sufficient LAN capacity and staff experience to review these submissions. CDER plans to complete the initial phase of the pilot project and issue a final report with recommendations by the end of 1995.

III. General Specifications for the Electronic Submission of Pharmacology and Toxicology Reports

A. Eligible Submissions

All preclinical P/T study reports are eligible for electronic submission. A paper copy must also be submitted.

B. Desirable Electronic Capabilities

—Complete text, tables, and graphics.
—Word search capability within a document and, if possible, between documents.
—Copy, print, cut, and paste capability.
—Index and abstract or document summary containing major subject and topic key words to facilitate document search and retrieval.

C. Hardware Specifications

—Optical disks (CDROM).
—Read only DOS diskettes.
—DOS 6.0 compatible hard disks.
—Tape, 4/8 millimeter.
—Hardware should be discussed with the Division of Information Systems Design (DISD) before submission.

D. Software Specifications

—WordPerfect 5.1 (DOS) or 6.0a (for Windows) or Microsoft Word 6.0.
—ASCII text with associated graphic format files (e.g., TIFF or equivalent for tables and graphics).
—Text/tabular format for tables is preferred.

E. Reviewer Access

Electronic submissions will be loaded into the CDER LAN by DISD. Electronic submissions will be accessible on personal computer workstations by authorized reviewers via the CDER LAN.

Dated: August 23, 1995.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 95–21452 Filed 8–29–95; 8:45 am]
BILLING CODE 4160–01–F

National Institutes of Health (NIH)

National Institute on Aging; Notice of Meeting of the National Advisory Council on Aging

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the National Advisory Council on Aging, National Institute on Aging, Wednesday, September 20, 1995, to be held at the National Institutes of Health, Building 1, Wilson Hall, Bethesda, Maryland. This meeting will be open to the public from 8:00 a.m. to 3:00 p.m. for a status report by the Director, NIA; a report on the Biology of Aging Program; a report on the Working Group on Program; and for a discussion of the NIA budget, program policies and issues, recent legislation, and other items of interest. Attendance by the public will be limited to space available.

In accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and section 10(d) of Public Law 92–463, the meeting of the Council will be closed to the public from 3:00 p.m. to adjournment for the review, discussion and evaluation of grant applications. The applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Ms. June McCann, Committee Management Officer for the National Institute on Aging, National Institutes of Health, Gateway Building, 7201 Wisconsin Avenue, Suite 2C218, Bethesda, Maryland 20892 (301/496–9322), will provide a summary of the meeting and a roster of committee members upon request.

Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact Ms. McCann at (301) 496–9322, in advance of the meeting.

(Catalog of Federal Domestic Assistance Program No. 93.866, Aging Research, National Institutes of Health)

Dated: August 23, 1995.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 95–21485 Filed 8–29–95; 8:45 am]
BILLING CODE 4140–01–M

National Institute of Nursing Research; Notice of Meetings of the National Advisory Council for Nursing Research and its Subcommittees

Pursuant to Public Law 92–463, notice is hereby given of the meeting of the National Advisory Council for Nursing Research, National Institute of Nursing Research, National Institutes of Health and its Subcommittee on September 7–8, 1995.

The meetings will be open to the public as indicated below. Attendance will be limited to space available.

The meetings will be closed to the public as indicated below in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. and section 10(d) of Public Law 92–463, for the review, discussion and evaluation of individual grant applications. These applications and discussions could reveal confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Summaries of meetings, rosters of committee members, and other information may be obtained from the Executive Secretary listed below. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should contact the Executive Secretary in advance of the meeting.

Name of Committee: National Advisory Council for Nursing Research.
Date of Meeting: September 7–8 1995.
Place: National Institutes of Health, Building 31, Conference Room 6, Bethesda, MD.
Open: September 7, 1:00 p.m. to 5:30 p.m.
Agenda: NINR Director's Report, Discussion: NIH Office of Behavioral & Social Sciences Research, Report of the Planning Subcommittee, Research Centers Program.